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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,307	01/11/2001	Sam J. Milstein	1946/1A483-US8	8759
7590	04/19/2006		EXAMINER	
DARBY & DARBY P.C. 805 Third Avenue New York, NY 10022			YEBASSA, DESTA LETTA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,307	MILSTEIN ET AL.	
	Examiner Dest L. Yebassa	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) See Continuation Sheet is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/16/2005, 07/27/04 and 03/15/04</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Request for Continued Examination (RCE) filed on 02/06/2006 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/06/2006 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176, and 178-195. are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 and 1 1-20 of U.S. Patent No. (6,071,538); claims 1-7 of U.S. Patent No. (5,714,167); 1-22 and 33-37 of U.S. Patent No. (6,348,207); and 1-39 of U.S. Patent No. (6,221,367). Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the claims of "538", "167", "207", and :"367" recite a method of delivering a biological agent comprising the same steps as that of instant claims i.e., a biologically active agent and a perturbant that reversibly transforms the active agent upon non- covalent binding with the active agent and together both the perturbant and the active agent form a supra molecular complex. The claims of the above patents recite the same perturbants as that claimed in the instant. The above patents fail to claim the instant routes of administration. However, absent evidence to the contrary it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the composition of the above patents containing an active agent and a perturbant that reversibly transform the active agent for administering via intranasal or sublingual or subcutaneous routes because the above patents recite the same mechanism of action of the perturbants in transporting the active agents, irrespective of the mode of administration i.e., the changed or altered confirmation of the active agents renders the active agent soluble to cross and penetrate the lipid bilayer membrane of the cells and resist enzymatic degradation. Accordingly, one of an ordinary skill in the art would have expected to transport the

active agents of using the perturbants across other mucosal membranes such as those of nasal tissues or the mouth cavity.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 13-16, 22-26, 31-36, 50-53, 59-62, 68-73, 87-90, 96-99, 105-110, 112-127, 131-137, 139-150, 152-163, 165-176, and 178-195 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al (US Patent No. 4,746,675) in view of Morishita et al (US Patent No. 4,873,087).

Makino et al. teaches external pharmaceutical composition for administering therapeutic agents via skin and mucosal membranes. The compositions of Makino

comprise a pharmacologically active agent and a penetration enhancer, such as pyroglutamic acid derivatives (col. 4-8). The pyroglutamic acid derivatives shown by formula I (col. 4) of Makino read on the claimed acylated amino acid derivatives. Makino teaches a number of pharmaceutically active agents that can be administered using the above absorption enhancer (col. 10-12), which include those that are claimed in the instant application. Makino teaches that the penetration enhancers are capable of penetrating skin or mucosa and thus can enhance the absorption a wide range of (hydrophilic as well as hydrophobic) drugs; and also when administered by oral or injection route, the absorption enhancer prevents the drug from being degraded and maintain the effective blood levels over a long period of time (col. 3-4).

Makino et al. does not specifically teach carboxylic acid.

Morishita teaches a preparation containing an absorption promoter and a medically active agent for promoting absorption through a gastrointestinal organ such as colon, rectum or through vagina. The absorption promoter substance of Morishita is an N-acyl amino acid or N-acyl peptide derivative, of formula I (col. 1, lines 5-15, col. 3, lines 13-15) and is obtained by the reaction of an acid (R-COOH) with an amino acid or peptide. The carboxylic acids and amino acids used for preparing N-acyl amino acids are described in col. 4 and 6 and include those described in the instant specification. Among the medically active agent, Morishita describes hormones, such as insulin, antibiotics etc (col. 5, lines 25-68. Morishita does not specifically teach subcutaneous, intranasal or sublingual delivery routes, instead teaches administration through rectum or vagina, which are lined by mucosal membranes.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the composition of Makino et al. or Morishita et al. for administration of biologically active agent subcutaneously since Makino et al. teaches oral or injection route of administration and penetration enhancer, Morishita et al. teaches administration through rectum or vagina, which are lined by mucosal membranes.

The prior art recited as combined teach the limitations of the instant claims. The Therefore, the invention as whole has been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa, PhD

Patent Examiner

Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Continuation of Disposition of Claims: Claims pending in the application are 13-16,22-26,31-36,50-53,59-62,68-73,87-90,96-99,105-110,112-127,131-137,139-150,152-163,165-176 and 178-195.

Continuation of Disposition of Claims: Claims rejected are 13-16,22-26,31-36,50-53,59-62,68-73,87-90,96-99,105-110,112-127,131-137,139-150,152-163,165-176 and 178-195.